TISSUE ACQUISITION SYSTEM AND METHOD OF USE

This application is a Continuation-in-Part of U.S. application serial number 09/057,303, filed on April 3, 1998, entitled "Breast Biopsy System and Method" to Burbank *et al.*

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to a tissue sampling or removal system, and methods of sampling or removing tissue from a patient, and more particularly to a system and methods for sampling or removing tissue from a patient which maintains the integrity of the tissue sample.

Brief Description of the Related Art

It is often desirable and frequently necessary to sample or remove a portion of tissue from humans and other animals, particularly in the diagnosis and treatment of patients with cancerous tumors, pre-malignant conditions, and other diseases or disorders. Typically, in the case of cancer, particularly cancer of the breast, there is a great emphasis on early detection and diagnosis through the use of screening modalities, including physical examination, and particularly mammography, which is capable of detecting very small abnormalities, which are often not palpable during physical examination. When a physician establishes by mammography or other screening modality, e.g., ultrasound, that suspicious circumstances exist, a biopsy must be performed to capture tissue for a definitive diagnosis as to whether the suspicious tissue cells in the lesion are cancerous. Biopsy may be done by an open or percutaneous technique. Open biopsy, which is an invasive surgical procedure

involving cutting into the suspicious tissue and directly visualizing the target area, removes the entire mass (excisional biopsy) or a part of the mass (incisional biopsy). Percutaneous biopsy, on the other hand, is usually done with a needle-like instrument through a relatively small incision, performed either blindly or with the aid of an imaging device such as ultrasound, MRI, or the like, and may be either a fine needle aspiration (FNA) or a core biopsy. In FNA biopsy, individual cells or clusters of cells are obtained for cytologic examination and may be prepared such as in a Papanicolaou smear. In core biopsy, as the term suggests, a core or fragment of tissue is obtained for histologic examination which may be done via a frozen section or paraffin section.

The type of biopsy utilized depends in large part on circumstances present with respect to the patient, including the location of the lesion(s) within the body, and no single procedure is ideal for all cases. However, core biopsy is extremely useful in a number of conditions and is being used more frequently by the medical profession.

To arrive at a definitive tissue diagnosis, intact tissue is needed from an organ or lesion within the body. In most instances, only part of the organ or lesion need be sampled. However, the portions of tissue obtained must be representative of the organ or lesion as a whole. In the past, to obtain tissue from organs or lesions within the body, surgery had to be performed to locate, identify and remove the tissue. With the advent of medical imaging equipment (x-rays and fluoroscopy, computed tomography, ultrasound, nuclear medicine, and magnetic resonance imaging) it became possible to identify small abnormalities even deep within the body. However, definitive tissue characterization still requires obtaining adequate tissue samples to characterize the histology of the organ or lesion.

For example, mammography can identify non-palpable (not perceptible by touch) breast abnormalities earlier than they can be diagnosed by physical examination. Most non-palpable breast abnormalities are benign; some of them are

malignant. When breast cancer is diagnosed before it becomes palpable, breast cancer mortality can be reduced. However, it is often difficult to determine if pre-palpable breast abnormalities are malignant, as some benign lesions have mammographic features which mimic malignant lesions and some malignant lesions have mammographic features which mimic benign lesions. Thus, mammography has its limitations. To reach a definitive diagnosis, tissue from within the breast must be removed and examined under a microscope. Prior to the late 1980's, reaching a definitive tissue diagnosis for non-palpable breast disease required a mammographically guided localization, either with a wire device, visible dye, or carbon particles, followed by an open, surgical biopsy utilizing one of these guidance methods to lead the surgeon to the non-palpable lesion within the breast.

A very successful type of image guided percutaneous core breast biopsy instrument currently available is vacuum-assisted automatic core biopsy device. One such successful biopsy device is shown and disclosed in U.S. Patent No. 5,526,822 to Burbank et al, which is expressly incorporated by reference herein. This device, known commercially as the MAMMOTOME™ Biopsy System, which is available from Ethicon Endo-Surgery, Inc., a division of Johnson & Johnson, has the capability to actively capture tissue prior to cutting the tissue. Active capture allows for sampling through non-homogeneous tissues. The device is comprised of a disposable probe, a motorized drive unit, and an integrated vacuum source. The probe is made of stainless steel and molded plastic and is designed for collection of multiple tissue samples with a single insertion of the probe into the breast. The tip of the probe is configured with a laterally-disposed sampling notch for capturing tissue samples. Orientation of the sample notch is directed by the physician, who uses a thumbwheel to direct tissue sampling in any direction about the circumference of the probe. A hollow cylindrical cutter severs and transports the tissue samples to a tissue collection chamber for later testing.